JUN 2 2 2004

K041108

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT iScience Surgical Corporation
3696A Haven Avenue
Redwood City, CA 94063
Ron Yamamoto
Phone (650) 421-2700
FAX (650) 421-2701

TRADE NAME: Ophthalmic Microcannula

COMMON NAME: Ophthalmic Microcannula

CLASSIFICATION NAME: Ophthalmic Cannula
Endoilluminator

DEVICE DESCRIPTION

The iScience Surgical Ophthalmic Microcannula, or iTRACK, is a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye such as the anterior chamber and posterior segment, for infusion and aspiration of fluids during surgery, including saline and viscoelastics. The microcannula incorporates an optical fiber to allow transmission of light to the microcannula tip for surgical illumination and guidance.

INDICATION FOR USE

The iScience Surgical Ophthalmic Microcannula is indicated for fluid infusion and aspiration, as well as illumination, during surgery.

PREDICATE DEVICES

The iScience Surgical Ophthalmic Microcannula is substantially equivalent to the following predicate devices:

Company:	American Medical Devices, Inc
Device:	Endolight End Irrigating Endoilluminator
510(k):	K970882
Company:	Syntec, Inc.
Device:	True Light End Irrigating Endoilluminator
510(k):	K973293
Company:	Micron Surgical, Inc.
Device:	Weiss Retinal Cannula
510(k):	K010305

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The intended use and technological features of the iScience Surgical iTRACK Ophthalmic Microcannula do not differ from the legally marketed predicate devices. Both the iScience iTRACK and the predicate device(s) utilize similar materials and methods of operation.

SUMMARY OF PERFORMANCE DATA

The iScience Surgical iTRACK Ophthalmic Microcannula has been shown to conform to the following standards, practices, and guidances:

STERILIZATION

- ANSI/AAMI/ISO 11137-1994, *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization .*
- ANSI/AAMI/ISO 10993; *Biological Evaluation of Medical Devices-Part 1.*

SHELF-LIFE AND PACKAGING INTEGRITY

- ANSI/AAMI/ISO 11607-1997, *Packaging for Terminally Sterilized Medical Devices.*
- AAMI TIR, Guidance for ANSI/AAMI/ISO 11607-1997, *Packaging for Terminally Sterilized Medical Devices, 1997.*

The device also underwent testing to ensure that performance requirements were met.

CONCLUSION

Since the iScience Surgical iTRACK Ophthalmic Microcannula meets the requirements of the stated standards and embodies technological characteristics similar to the predicate devices, the device has been shown to be substantially equivalent to the predicate devices, is as safe and effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

iScience Surgical Corporation
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
2 Delphinus
Irvine, CA 92612

Re: K041108
Trade/Device Name: iScience Surgical Ophthalmic Microcannula
Regulation Number: 21 CFR 886.1500
Regulation Name: Endoilluminator
Regulatory Class: Class II
Product Code: MPA
Dated: April 27, 2004
Received: April 30, 2004

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 INDICATION FOR USE STATEMENT

510(k) Number (if known): K041108

Device Name: iScience Surgical Ophthalmic Microcannula

Indications for Use:

The iScience Surgical Ophthalmic Microcannula is indicated for fluid infusion and aspiration, with illumination, during surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ ***OR*** ***Over-The-Counter Use*** ____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K041108